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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/520,221

07/27/2005

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GJE7140

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23557 7590 04/25/2008  
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EXAMINER

WOOD, AMANDA P

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

04/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/520,221 | <b>Applicant(s)</b><br>LOWE ET AL. |  |
|                              | <b>Examiner</b><br>AMANDA P. WOOD    | <b>Art Unit</b><br>1657            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's response and amendments filed 30 January 2008 have been received and entered.

Claims 1-6 and 8-13 are pending.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 30 January 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application Serial No. 10/520,323 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-6 and 8-13 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al (WO 95/26499) as cited in the IDS filed on 18 February 2005.

A method and device is claimed for detection of a cell, wherein said method comprises immobilising a cell in a device also containing a sensor, and introducing a growth medium, wherein the sensor is sensitive to a product of the cell's growth; detecting any change in an optical characteristic of the sensor; wherein the sensor is a holographic sensor.

Lowe et al beneficially teach a sensor comprising a hologram supported on or within a holographic support medium, wherein examples of such holographic support media can be agar or agarose (i.e., growth medium), see for example, Abstract and page 12, lines 5-20. In addition, Lowe et al teach that a species to be detected is reactive with a substance disposed throughout the sensor, and that a specific binding conjugate of a species to be detected, such as an antibody, may be disposed throughout the sensor (see, for example, Abstract and page 13, lines 1-15).

Furthermore, Lowe et al particularly teach that the species to be detected may include cells, bacteria, fungi, and yeasts, among other analytes (see, for example, page 12, lines 20-30). Lowe et al beneficially teach that judicious selection of hologram type, fabrication technique, and analyte species permits a number of different sensors to be produced, to be tailored to detect specific compounds, events and biological species. Lowe et al further teach that sensitivity may be varied by careful choice of specific binding conjugate, type of hologram and fabrication technique used (see, for example, page 11, lines 15-30).

Based upon the beneficial teachings provided within Lowe et al, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was

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made to modify the method and device disclosed by Lowe et al to provide a method and device suitable for the detection of a cell, wherein the cell is immobilized in a device also containing a sensor, and introducing a growth medium, wherein the sensor is a holographic sensor, discussed above. Furthermore, Lowe et al beneficially teach that immuno-type sensors such as that taught above can be tailored to detect specific compounds, events, or biological species, and that sensitivity can be varied with careful choice of specific binding conjugate, type of hologram and fabrication technique used. The result-effective adjustment of particular conventional working conditions (e.g., a particular means to immobilize the cell or bacteria, and a particular species of bacteria) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claims allowed.

Please note that the examiner assigned to the instant application has changed. Accordingly, any inquiry concerning this communication or earlier communications

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should be directed to examiner Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW  
Examiner  
Art Unit 1657

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655